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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,222	12/20/2001	Ranjani V. Parthasarathy	57314US002	9052

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER
HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 07/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/027,222	Parthasarathy et al.
Examiner	**Art Unit**
Dwayne K. Handy	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒. This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above, claim(s) 1-38 and 46-52 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 39-45 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-38, drawn to methods of removing small negatively charged particles from a sample, classified in class 436, subclass 175.

II. Claims 39-45, drawn to a device for removing small negatively charged particles from a sample, classified in class 422, subclass 102.

III. Claims 46-52, drawn to a container with an adhesive cover for removing small negatively charged particles from a sample, classified in class 220, subclass 359.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II/III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used for performing chemical reactions in array form including multiple chemical reactions in the device which contains the array.

3. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention II appears to claim a device with a plurality of process arrays, each comprised of a plurality of chambers defining a volume and connected by a distribution channel. Invention III appears to claim a container covered by an adhesive. Invention II, then, would comprise a device which also processes the sample in addition to simply holding it in a container. This would be a different mode of operation.

4. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group II, restriction for examination purposes as indicated is proper.

5. In response to a Restriction in a previous Office Action, a provisional election was made with traverse to prosecute the invention of a device for removing small negatively charged particles from a sample, claims 39-45. Affirmation of this election was made by applicant in replying to this Office action. Claims 1-38 and 46-52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The Examiner has re-written the Restriction requirement. The new requirement includes only 3 groups and no election of species in the method claims. The Examiner did, however, restrict between the two devices. The Examiner assumes applicant wishes to traverse the rewritten Restriction as well. Claims 39-45 have been Examined in this action.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

a timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. a terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 39-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-61 of copending Application No. 10/417,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 10/417,609 are narrower in scope than those of the instant application. Therefore claims 39-45 are anticipated by claims 53 and 56-61 of Application No. 10/417,609. See In re Goodman.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 39-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-53 of copending Application No. 10/027,226 in view of Nelson et al. (6,344,326). Claims 50-53 of copending Application No. 10/027,226 teach every element of claims 39-42 except for anion exchange material as the solid phase extraction material. Nelson teaches the use a wide variety of solid phase extraction materials in disclosing their separation device (column 8, lines 15-29) including anion exchange material. It would have been obvious to one of ordinary skill in the art to combine the anion exchange material with the device of Application No. 10/027,226. One would

add the anion exchange material to perform separations of materials such as nucleic acids and protein which specifically bind to such material.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 39-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. (6,344,326). Nelson et al. teach a microfluidic device for nucleic acid separation and processing. The device is comprised of a number of channels containing fluid control elements and separation media disposed on a substrate. The basic embodiment of the device is described in columns 4 and 5 and includes inlet and outlet passages as well as channels for distributing solutions through the various channels of the device. Nelson teaches the use of separation media in conjunction with the channels in column 8:

(15) Suitable capture media for proteins include the following. Suitable capture media for proteins include: ion exchange resins, including anion (e.g., DEAE) and cation exchange; hydrophobic interaction compounds (e.g., C4, C8 and C18 compounds); sulfhydryls; heparins; inherently active surfaces (e.g., plastics, nitrocellulose blotting papers); activated plastic surfaces; aromatic dyes such as Cibacron blue, Remazol orange, and Procion red. For carbohydrate moieties of proteins, lectins, immobilized hydrophobic octyl and phenylalkane derivatives can be suitable. For enzymes, analogs of a specific enzyme substrate-product transition-state intermediate can be suitable; for kinases, calmodulin can be suitable. Suitable capture media for receptors include receptor ligand affinity compounds.

(16) As mentioned above, the enrichment channel will comprise at least one inlet and at least one outlet. Of course, where there is a single inlet, the inlet must serve to admit sample to the enrichment channel at an enrichment phase of the process, and to admit an elution medium during an elution phase of the process. And where there is a single outlet, the outlet must serve to discharge the portion of the sample that has been depleted of the fraction retained by the enrichment media, and to pass to the main electrophoretic microchannel the enriched fraction during the elution phase. Depending on the particular enrichment means housed in the enrichment channel, as well as the particular device configuration, the enrichment channel may have more than one fluid inlet, serving as, e.g., sample inlet and elution buffer inlet; or the enrichment channel may have more than one outlet, serving as, e.g., waste outlet and enriched fraction fluid outlet. Where the enrichment channel is in direct fluid communication with the main electrophoretic channel, i.e., the enrichment channel and main electrophoretic flowpath are joined so that fluid flows from the enrichment channel immediately into the main electrophoretic flowpath, the enrichment channel will comprise, in addition to the waste outlet, an enriched fraction fluid outlet through which the enriched fraction of the sample flows into the main electrophoretic flowpath. When convenient, e.g., for the introduction of wash and/or elution solvent into the enrichment channel, one or more additional fluid inlets may be provided to conduct such solvents into the enrichment channel from fluid reservoirs. To control bulk fluid flow through the enrichment channel, e.g., to prevent waste sample from flowing into the main electrophoretic flowpath, fluid control means, e.g., valves, membranes, etc., may be associated with each of the inlets and outlets. Where desirable for moving fluid and entities through the enrichment channel, e.g., sample, elution buffer, reagents, reactants, wash or rinse solutions, etc., electrodes may be provided capable of applying an electric field to the material and fluid present in the enrichment channel.

(17) The next component of the subject devices is the main electrophoretic flowpath. The main electrophoretic flowpath may have a variety of configurations, including tube-like, trench-like or other convenient configuration, where the cross-sectional shape of the flowpath may be circular, ellipsoid, square, rectangular, triangular and the like so that it forms a microchannel on the surface of the planar substrate in which it is present. The microchannel will have cross-sectional area which provides for capillary fluid flow through the microchannel, where at least one of the cross-sectional dimensions, e.g., width, height, diameter, will be at least about 1 mm, usually at least about 10 mm, but will not exceed about 200 mm, and will usually not exceed about 100 mm. Depending on the particular nature of the integrated device, the main electrophoretic flowpath may be straight, curved or another convenient configuration on the surface of the planar substrate.

12. Claims 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Swedberg et al. (6,450,047). Swedberg et al. teach a device for high through put sample processing. The device is best shown in Figures 1A-2B, and described in column 10. The device includes a plurality of process chambers connected by a channel and the use of separation media. Various separation media types are disclosed in column 9 and includes anionic exchange material.

Inventorship

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (6,344,326) in view of Gjerde et al. (6,265,168). Nelson, as described in paragraph 11 above, teaches every element of claims 43-45 except for an anion exchange material partially coated with a negatively charged polymer. Gjerde et al. teach an apparatus for separating and purifying nucleic acids. The device is comprised of a tube having an upper input chamber, a lower eluent receiving chamber and a fixed unit of separation media supported therein. The separation media used by Gjerde which is most relevant to the instant application is described in column 30:

(133) The materials used currently in the MIPC column matrix of this invention, as well as other materials suitable for MIPC (as one example, larger polymeric particle sizes of nonporous reverse-phase materials), are known to have an exceptionally high capacity and selectivity for long-chain nucleic acids. By applying

a suitable pairing ion, and then changing nothing other than the acetonitrile concentration (or any other suitable solvent, such as an alcohol), the quantitative adsorption/desorption of varying lengths of short- and long-chain nucleic acids are essentially turned on and off. Furthermore, since the matrix is made of a nonporous polymeric material, there is no opportunity for interlopers (dNTPs, primers, primer dimers, non-specific amplification products) to get trapped and become problematic downstream. In essence, the matrix materials we possess (nonporous polystyrene-divinylbenzene, either unalkylated or alkylated) are perfectly suited to the purification of PCR products prior to the most demanding molecular biology applications. Also suitable are nonporous polymeric or modified silica materials which has been manufactured or purified in a manner which produces surfaces which are free of contamination. These can be in the form of beads, monoliths, channels, capillary or planar surfaces. The polymeric surfaces can be provided by non-alkylated and alkylated materials including polystyrene, divinylbenzene, hydroxyethylmethacrylate, and other nonionic polymers. **Polymers having a negative charge may also be used** provided the charged groups are protonated to produce a neutral surface, i.e., carboxylic acid. An example of this is illustrated by Example 1. When trying to do size-based cloning from a pool of fragments (cDNA fragment pools, fragment pools from restriction digestion of plasmids/artificial chromosomes/genomic DNA, etc), the efficiency of fragment ligation into the vector (and hence cloning efficiency) is biased towards smaller fragments. As an extension of the identical principles applied for purification of PCR products, one can perform fractionations of fragment pools on the kits. By applying gradually increasing concentrations of acetonitrile and analyzing the collected fractions with a suitable 260/280 detector, an extremely rapid process is created that effectively replaces smearing the fragment pools out on a gel and slicing the size range of interest out with a razor blade. This general process has been shown for high-pressure sizing of fragments prior to cloning, and will translate directly into low-pressure formats.

It would have been obvious to one of ordinary skill in the art to combine the negatively charged polymers of Gjerde to the anionic exchange material of Nelson. One would add the negatively charged polymer to obtain the benefit of the "quantitative adsorption/desorption of varying lengths of short- and long-chain nucleic acids" that can be turned on and off through the proper combination of matrix materials as described in Gjerde et al. It would also have been obvious to one of ordinary skill in the art to provide the negatively charged polymeric material in a known pattern. One would provide the known pattern in order to identify sample material which attaches to the matrix based on the location of their attachment.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dusterhoft et al. (6,451,260), Muscate-Magnussen (US 2002/0046966), Ingenhoven et al. (US 2002/0182114), Zare et al. (2003/0062310), Gundel et al. (2001/0045000), Jedrzejewski et al. (2003/0013203), and Andersson et al. (2003/0053934) teach separation devices which use solid phase extraction media.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

June 29, 2003